REMARKS-General

The currently amended independent claim 51 incorporates all structural limitations of the original claim 1 and includes further limitations previously brought forth in the disclosure. No new matter has been included. All new claims 74-81 are submitted to be of sufficient clarity and detail to enable a person of average skill in the art to make and use the instant invention, so as to be pursuant to 35 USC 112.

With regard to the rejection of record based on prior art, Applicant will advance arguments to illustrate the manner in which the invention defined by the newly introduced claims is patentably distinguishable from the prior art of record. Reconsideration of the present application is requested.

Response to Rejection of Claims 51-73 under 35USC112

The applicant submits that the currently amended claims 51, 60, 69, the previous presented claims 52-59 and 65-68 and the newly drafted dependent claims 74-81 particularly point out and distinctly claim the subject matter of the instant invention, as pursuant to 35USC112.

Response to Rejection of Claims 51-73 under 35USC103

The Examiner rejected claims 51-73 (which correspond to claims 51-81 in the present amendment) over Jiang et al. and Song et al. in view of Nishimura et al., Ebrup et al. Gorogawa et al., Hamaoka et al and Yoshikawa. Pursuant to 35 U.S.C. 103:

"(a) A patent may not be obtained thought the invention is **not identically** disclosed or described as set forth in **section 102 of this title**, if the **differences** between the subject matter sought to be patented and the prior art are such that the **subject matter as a whole would have been obvious** at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made."

In view of 35 U.S.C. 103(a), it is apparent that to be qualified as a prior art under 35USC103(a), the prior art must be cited under 35USC102(a)~(g) but the disclosure of the prior art and the invention are not identical and there are one or more differences between the subject matter sought to be patented and the prior art. In

addition, such differences between the subject matter sought to be patented **as a whole** and the prior art are obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains.

In other words, the differences between the subject matter sought to be patent as a whole of the instant invention and Jiang which is qualified as prior art of the instant invention under 35USC102(b) are obvious in view of the various cited art at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains.

The applicant respectfully submits that in order to determine whether the differences between the subject matters sought to be patent as a whole of the instant invention and the primary prior arts, Jiang and Song, are obvious in view of the supplemental cited arts, Nishimura et al., Ebrup et al. Gorogawa et al., Hamaoka et al. and Yoshikawa, we have to identify all the differences between the claims of the instant inventions and Jiang and Song. The applicant respectfully identifies the differences between the claims of the instant invention and Jiang and Song as follows.

Referring to the newly amended claim 51, the composition is used for treating living object with non-insulin dependent diabetes mellitus by restoring insulin beta cells, whereas Jiang et al. merely uses Berberine as a supplement and Song merely provides information for the possibility of some therapeutic effect of Berberine. A mere recitation of possible therapeutic effect does not in any way anticipate or suggest any composition for treating living object with non-insulin dependent diabetes mellitus **through restoration of insulin beta cells**. Experiments have shown a promising effect of restoring insulin beta cells by administering berberine and catalpol. This is an **unexpected result** from combining the two active ingredients. The results as demonstrated in Example 13 in relation to the seven indexes, that is: (1) fasting plasma sugar level before and after treatment (FPG), (2) Apolipoprotein Al (APOAl), (3) Apolipoprotein B (APOB), (4) total cholesterol (TC), (5) Triglyceride (TG), (6) High density lipoprotein (HDL), and (7) Low density lipoprotein (LDL) has further support the unexpected results which is only achieved by the subject matter of the present invention. Neither Jiang nor Song and the related cited arts in any way teach, suggest or motivate the use of the two claimed active ingredients for lowering blood glucose level and risk of complications through restoration of insulin beta cells in living objects such as mice.

In the newly amended claim 51, "the composition comprises a berberine as a first active ingredient and a catalpol as a second active ingredient". Jiang et al. merely teaches the use of berberine as an additional composition for use with insulin in which the object is to boost up the effect of insulin. The use of insulin is contradictory to the rationale of using the composition and is in a way teaches away from the present invention. Song et al. merely provides research data of berberine and is silent on its application or combination effect with other composition. There is no indication of its application or combination effect with Catapol which is the second active ingredient of the present invention. While Jiang et al. teaches away from the present invention, Song et al. is insufficient in having any implication to the present invention, the prima facie case of obviousness is not fully demonstrated by Jiang et al and Song et al. in view of other references.

The applicant further submits that each of the cited references, Jiang et al., Song et al., Nishimura et al., Ebrup et al. Gorogawa et al., Hamaoka et al. and Yoshikawa merely teaches one of the ingredients of the composition as claimed in the instant invention. However, none of the cited references teaches the composition in a whole in combination of all the elements in specific as claimed in claims 51-60, 65-69 and 74-81. The applicant respectfully submits that the cited references fail to anticipate the distinctive features of the instant invention as claimed. No specific range such as 1 to 300 mg/kg/dl of berberine (as in claims 57, 58, 65-68); dosage of 300mg of berberine and catalpol (as in claims 74, 75); relative ratio of 1:20 to 20:1 by weight of berberine and catalpol (as in claims 76-77) are provided by the references.

Combination of Elements

The Court of Appeal of the Federal Circuit has stated, "[V]irtually all [inventions] are combinations of old elements." *Environmental Designs, Ltd. V. Union Oil Co.*, 713 F.2d 693, 698, 218 USPQ 865, 870 (Fed. Cir. 1983); see also *Richdel, Inc. v. Sunspool Corp.*, 714 F.2d 1573, 1579-80, 219 USPQ 8, 12 (Fed. Cir. 1983). Thus, "[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *In re Fine*, 5 USPQ 2d 1600 (Fed. Cir. 1988).

In other words, the Office Action cannot, based on hindsight gained from the applicant's invention, argue that it is obvious to combine two compositions each of which

is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The obviousness cannot be shown by combining the teachings of the prior art unless there is some teaching or incentive supporting the combination. *ACS Hospital Systems, Inc. v. Montefiore Hospital,* 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984); *In re Geiger*, 815 F.2d at 688, 2 USPQ2d at 1278 (Fed. Cir. 1987).

The applicant respectfully submits that in tradition Chinese medicine theory, Chinese medicine can be divided into a **primary medicine and secondary medicine**, wherein the primary medicine is responsible for proving an active treatment effect to a particular disorder, while the second medicine provides for supplemental treatment effect. The difference between Chinese medicine and western medicine is that the division of medicine into primary medicine and secondary medicine **does not mean that the particular composition can still function to treat the particular disorder even without the aid of secondary medicine**. This has stark contrast with western medicine because the inactive ingredient of a particular composition can often be interchanged with other ingredient because inactive ingredient is basically not effective in treating the targeted disease. This is the reason why inactive ingredient can easily be substituted by other ingredient and this is often the basis of obviousness rejection under 35USC103(a). In Chinese medicine, however, the primary and the second medicine and any other ingredient **must be** present and must have a predetermined volume or weight ratio in order to be effective. Substantial variation of the ratio (even for secondary medicine) would substantially destroy the disease curing ability of the Chinese medicine.

Even with the category of secondary medicine, there exist many different varieties. For example, some secondary medicine is primarily used for treating related complication arising from a main disease, yet some other secondary medicine would be responsible for reinforcing the body strength of the patient. When the body strength of the patient is reinforced, the effectiveness of the primary medicine can be substantially enhanced, and the overall treatment effect of the medication is also enhanced.

Another kind of secondary medicine usually aims to reduce the side-effect of the primary medicine. For example, if a particular type of primary medicine is used, and if that primary medicine has certain side-effect, the second medicine is used for either proving relief to that side-effect, or neutralizing the side-effect causing component of the

primary medicine. In traditional Chinese medicine theory, each particular herb may assume more than one role. For example, a particular herb may assume the role of primary medicine and one particular kind of secondary medicine (e.g. reinforcing body strength). On the other hand, another particular type of herb may assume the role of secondary medicine but having a variety of functions. For example, a particular herb may simultaneously reinforce body strength and relieve side effect coming from the application of the primary medicine. The applicant must reiterate that the exact composition of every kind of Chinese medication **is a result of extensive experimentation and clinical trials**. It is nearly **impossible** for one to predict the overall outcome of a predetermined combination of different individual herbs. One may be familiar with the general treatment effect of a particular herb, but when it is combined with other herbs, no theoretical basis exist for predicting the overall outcome of the combined medication. This is the well-known practice for Chinese medicine which has existed for thousands of years in China. In the instant invention, the combination suggested by the examiner requires extensive experimentation under the above mentioned practice.

Moreover, the Federal Circuit in In re Dembiczak, 175 F.3rd 994, 50 USPQ2d 1614 (Fed. Cir. 1987) deprecated rejections based upon "a hindsight-based obviousness analysis" and emphasized that what is required is a "rigorous application of the requirement for a showing must be clear and particular" and that broad conclusory statements regarding the teaching of multiple references and "a mere discussion of the ways that the multiple prior art references can be combined to read on the claimed invention" is inadequate. Absent an explicit suggestion or teaching of the combination in the prior art references, there must be "specific....findings concerning the identification of the relevant art, the level of ordinary skill in the art, the nature of the problem to be solved, or any other factual findings that might serve to support a proper obviousness analysis".

In addition, were a claimed relationship between variables or parameters is not discussed or suggested by a prior art reference, such reference cannot render such relationship of variables obvious unless such variables are inherent. See In re Rejckaert, 9F.3d 1531 (Fed. Cir. 1993) ("the Commissioner points out that in the recording art, the exact matching of signal time to recording time is an optimal condition,

and that this condition would be met by fulfilling the claimed relationship. While the condition described may be an optimal one, it is not 'inherent' in Awamoto. Nor are there means to achieve this optimal condition disclosed by Awamoto, explicitly or implicity.")

In this case, the cited references, Jiang et al., Song et al., Nishimura et al., Ebrup et al. Gorogawa et al., Hamaoka et al. and Yoshikawa not only fails to suggest the claimed relationship and effective range of the ingredients, inherently or otherwise; it cannot possibly achieve it. Each of the cited references merely teaches individual chemical with potential effect and may be formulated into nutritional supplements. However, none of the cited references suggests the exact combination in relationship. Without the claimed relationship, effective range and percentage ratio of the ingredients as claimed, there is no way to achieve the present invention.

Indeed, the only mention of relationship and percentage of all the combining elements to form the composition as claimed is in applicants own specification and claims. Accordingly, it appears that the Examiner has fallen victim to the insidious effect of a hindsight analysis syndrome where that which only the inventor taught is used against the teacher in *W.L Gore and Associates v. Garlock, Inc.*, 220 USPQ 303, 312-313 (Fed. Cir. 1983) cert. denied, 469 U.S. 851 (1984).

In view of the argument set forth in the previous amendments and the above, the applicant believes that for all of the foregoing reasons, all of the claims are in condition for allowance and such action is respectfully requested.

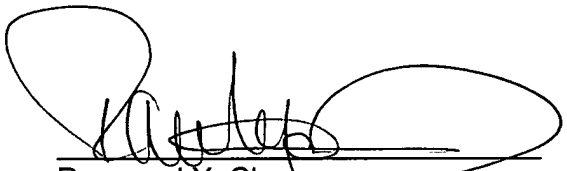
The Cited but Non-Applied References

The cited but not relied upon references have been studied and are greatly appreciated, but are deemed to be less relevant than the relied upon references.

In view of the above, it is submitted that the claims are in condition for allowance. Reconsideration and withdrawal of the rejection are requested. Allowance of claims 51-60, 65-69, 74-81 at an early date is solicited.

Should the examiner believes that anything further is needed in order to place the application in condition for allowance, he is requested to contact the undersigned at the telephone number listed below.

Respectfully submitted,



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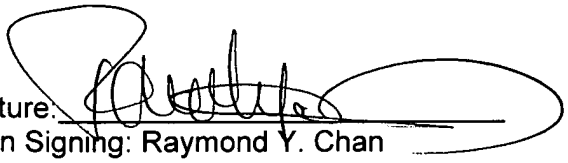

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